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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/807,506	02/27/1997	VICTOR SMIT	236841/BO410	5096

22242 7590 04/19/2004

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/807,506	SMIT ET AL.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2002*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *94-132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *94-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Final Office Action is responsive to the amendment and remarks submitted December 31, 2002.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 94 and 122 were rejected as being vague and indefinite for the recitation of "is introduced." This rejection is withdrawn. Claim 100 was rejected as being vague and indefinite for reciting "LDMS." This rejection is withdrawn. Claims 104, 109, 111, 113, 115, 125 and 127 were rejected as being vague and indefinite for reciting "and/or." This rejection is withdrawn. Claims 104, 108, 109, 121 and 130 were rejected as being vague and indefinite for reciting "e.g.," "for example," or "for instance." This rejection is withdrawn only as to claims 104, 108 and 109. Claim 104 was rejected as being vague and indefinite for reciting "gradually varying conditions." This rejection is maintained. Claims 107 and 112-114 were rejected as being vague and indefinite for reciting "close proximity." This rejection is maintained. Claim 112 was rejected as being an improper Markush claim for reciting "and a colony stimulating factor." This rejection is withdrawn. Claim 113 was rejected as being vague and indefinite for reciting "same (cytokine) superfamily." This rejection is maintained. Claim 119 was rejected as being vague and indefinite for reciting "almost 50%." This rejection is withdrawn. Claim 123 was rejected as being vague and indefinite for reciting "significant inhibition." This rejection is withdrawn. Claim 132 was rejected as being vague and indefinite for reciting "any of the method steps of claim 94." This rejection is withdrawn. Claim 126 was rejected as improperly depending from a method claim. This rejection is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 104, 107, 112-114, 121 and 130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 104 was previously rejected as being vague and indefinite for reciting "gradually varying conditions." The Examiner asserted this language failed to clarify the extent and the rate at which the conditions were varied. Applicants have amended claim 104 to recite "while gradually varying . . . pH in a range between a pH of 5.0 and 7.0." While Applicants' amendment clarifies the extent to which the conditions are varied, it does not clarify the rate at which conditions are varied. Accordingly, claim 104 is rejected under 35 U.S.C. 112, second paragraph as being impermissibly vague.

Claims 107 and 112-114 were rejected as being vague and indefinite for reciting "close proximity." Applicants have amended the claims to recite "in a such close proximity to a metal binding center that it effects a feature selected from the group consisting of biological and chemical features." This amendment does not overcome the rejection because the distance between the modification and the metal binding center remains unclear. A modification to a protein could dramatically affect its conformation, and therefore its "biological features," regardless of the distance between the modification and a metal binding site. Accordingly, claims 107 and 112-114 are impermissibly vague.

Claim 113 is rejected as being vague and indefinite for reciting "and a member of the same (cytokine) superfamily." This language renders the claim indefinite because it is unclear

whether the term "cytokine" actually modifies the term "superfamily." Thus, the scope of claim 113 is impermissibly vague.

Claims 121 and 130 are rejected as being vague and indefinite for reciting "e.g.." This language renders the claim indefinite because it is unclear whether the limitations following "e.g." are within the scope of the claim. Accordingly, claims 121 and 130 are rejected as being impermissibly vague.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 125-127 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is directed to methods for treating HIV infection by lowering antibody levels. As noted in the prosecution history, one skilled in the art would not expect the lowering of antibody levels in a host to suppress or inhibit infection. Nor does the specification establish that lowering any antibody level would result in inhibition of HIV infection.

Claims 94-132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is

directed to methods and substances modified in a number of ways to produce effects that are alleged to be suitable in therapeutic methods of stimulating stem cell replication, treating and/or preventing HIV infection, or for gene therapy. As noted in the prosecution history, the outcome of protein modification is uncertain as even single amino acid changes can have drastic effects on protein conformation and protein function. Thus, one of ordinary skill would not expect the full scope of modifications claimed by Applicants to have any therapeutic benefit. Accordingly, claims 94-132 are rejected for the reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tmb

ULRIKE WINKLER, PHD.
PATENT EXAMINER 4/16/04